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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,786	02/08/2002	Eugene O. Major	2370-67	9275

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT PAPER NUMBER

1649

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,786

Applicant(s)

MAJOR ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 12, 13, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12, 13, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/14/06 has been entered.

2. Applicant's arguments filed 6/14/06 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-4, 12-13 & 33-34 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14 & 16 of U.S. Patent No. 5,753,491, for the reasons made of record in Paper NOs: 1/31/05 & 20051012, and as follows.

In contrast to Applicants' assertions on pages 4-5 of the response, changing the claims from "comprising to "consisting essentially of" is still open claim language, and therefore, still encompass immortal human multipotent CNS neural stem cells, as claimed in '491, for the reasons previously made of record. As Applicants admit for the record, "[m]ultipotent stem cells

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can be either cholera-toxin negative or cholera-toxin positive". Thus, inherency is an issue.

Therefore, "491 clearly encompasses that now claimed. It should be noted that the sole reason this is not a statutory double patent rejection is because the claims are not identical.

Nevertheless, the issue remains that Applicants are not permitted to extend the patent term of that claimed in '491 through this application.

5. Claims 1-4, 12-13 & 33-34 stand rejected under 35 U.S.C. 102(e) as being anticipated by Major et al (U.S. Patent 5,753,491; IDS Ref #2), for the reason made of record in Paper NOs: 1/31/05 & 20051012, and as follows.

In contrast to Applicants' assertions on pages 5-6 of the response, changing the claims from "comprising to "consisting essentially of" is still open claim language, and therefore, still encompass Major's immortal human multipotent CNS neural stem cell line, because similar methods are used to generate both Major's and the multipotent immortal CNS stem cell lines of the instant invention; thereby, reasonably also encompassing ChTx negative neural stem cells. Simply put, similar methods reasonably and inherently result in structurally identical products.

In summary, Major et al disclose isolated, immortalized CNS human fetal neuro-derived cell lines, which "generally produce progenitor neuronal and glial cells" (e.g., column 7, lines 22-37); thereby, being multipotent, by definition (i.e., as it relates to claims 1-3, 12 & 33). Cells derived from SVG cells are also described by Major (e. g., column 4, lines 66 - column 5, line 1; column 7, lines 57-65), which further appear identical to those cells (i.e., multipotent cells) described on pgs 3 & 15-17 of the instant specification (i.e., as it also relates to claims 1-3, 12 and 33). In that all of these cells described by Major et al reasonably appear identical to the

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alternative names of “NG1, NG2 and NG3” cells recited in claim 13, and inherently express markers that uniquely define what constitutes a multipotent stem cell, the limitations of claims 4 and 13 are met; absent evidence to the contrary. Finally, in that the process of producing multipotent neural stem cells does not materially change the multipotent neural stem cell product produced, the limitations of claim 34 are anticipated.

6. Claims 1-4, 12-13 & 33-34 stand rejected under 35 U.S.C. 102(e) as being anticipated by Weiss et al (U.S. Patent 5,750,376; IDS Ref #3), for the reason made of record in Paper NO: 1/31/05 & 20051012, and as follows.

In contrast to Applicants’ assertions on page 7 of the response, changing the claims from “comprising to “consisting essentially of” is still open claim language, and therefore, still encompass Weiss’ human multipotent CNS neural stem cell lines. Again, as previously made of record, no product-by-process steps have been used to generate the multipotent immortal cell lines of the instant invention that separate ChTx negative cells from putative ChTx positive cells.

In summary, Weiss et al disclose isolated human CNS multipotent neural stem cell lines (i.e., neurospheres; as it relates to claims 33-34), which are clonally-derived/ “immortalized” and have the “potential to differentiate toward a neuronal cell or a glial cell” (e.g., column 11, lines 49-56) columns 13, 17- 18, 21-22, 36 and 48; as it relates to claims 1-3 and 12). In that the multipotent stem cells described by Weiss et al reasonably appear identical to the alternative names of “NG1, NG2 and NG3” cells recited in claim 13, and inherently express markers that uniquely define what constitutes a multipotent neural stem cell (e. g., column 56), the limitations of claims 4 and 13 are met; absent evidence to the contrary. Finally, in that the process of

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producing multipotent neural stem cells does not materially change the multipotent neural stem cell product produced, the limitations of claim 34 are anticipated.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
August 30, 2006

**ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER**